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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/010,723	12/06/2001	Mark G. Allen	BVTP-P04-506	4309

7590

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AGNES S. LEE
ROPES & GRAY
ONE INTERNATIONAL PLACE
BOSTON, MA 02110-2624

EXAMINER

THOMPSON, KATHRYN L

ART UNIT

PAPER NUMBER

3763

DATE MAILED: 05/18/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/010,723

Applicant(s)

ALLEN, M

Examiner

Kathryn L. Thompson

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 February 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1 and 49-72 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 49-72 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 49, 54-66, 70, and 71 are rejected under 35 U.S.C. 102(b) as being anticipated by PCT WO 97/03718. Eicher et al teach a device for transporting a material across a biological barrier, the device comprising one or more microneedles having at least one substantially annular channel therethrough and having a length between about 1 μ m and 1mm and a diameter between about 1 μ m and 100 μ m and a substrate to which the one or more microneedles is attached wherein the substrate and/or the microneedles are formed from flexible materials to allow the device to fit the contour of the biological barrier (Figure 1).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 50-53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eicher et al. Eicher et al does not disclose expressly that the diameter of the one or more microneedles is between about 10 μm and 30 μm , 20 μm and 50 μm , 30 μm and 100 μm , and wherein the diameter of the substantially annular channel is between about 3 μm and 80 μm . At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to make the measurements of the aforementioned diameters because Applicant has not disclosed that making microneedles with these specific measurements provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well.

Claims 67 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eicher et al in view of Gerstel et al (US 3,964,482). Eicher et al teaches all of the claimed limitations except the one or more microneedles including a non-biodegradable polymer selected from polycarbonate, polymethacrylic acidm ethylenevinyl acetate, polytetrafluorethylene, and polyesters. Gerstel et al teach the one or more microneedles including a non-biodegradable polymer selected from polycarbonate, polymethacrylic acidm ethylenevinyl acetate, polytetrafluorethylene, and polyesters. It would have been obvious to one with ordinary skill in the art to use the teachings of Gerstel et al to modify the invention of Eicher et al and include non-biodegradable polymers as a material that the microneedles can be made of since non-biodegradable polymers are notoriously well known in the art as possible materials from which medical devices can be fabricated.

Claim 69 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eicher et al in view of Godshall et al (US 5,879,326). Eicher et al teaches all of the claimed limitations except wherein the one or more microneedles are formed by a micromachining technique. Godshall et al teach wherein the one or more microneedles are formed by a micromachining technique (Column 3, Lines 44-48). It would have been obvious to one with ordinary skill in the art to use the teachings of Godshall et al to modify the invention of Eicher et al to include that the microneedles are formed by a micromachining technique since micromachining is notoriously well known in the art as a method of fabrication for microneedles.

Claim 72 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eicher et al in view of Godshall et al. Eicher et al discloses all of the claimed limitations except a transport control mechanism for generating an ultrasonic force gradient for causing the material to move across a biological barrier. Godshall et al does disclose a transport control mechanism for generating an ultrasonic force gradient for causing the material to move across a biological barrier (Column 2, Lines 7-16). It would have been obvious to one with ordinary skill in the art to use the teachings of Godshall et al to modify the invention of Eicher et al since according to Godshall et al the use of a transport control mechanism that generates an ultrasonic force gradient is used to increase the migration of the drug across the skin barrier and improve absorption.

Response to Arguments

Applicant's arguments filed on February 17, 2005 have been fully considered but they are not persuasive. Applicant states that Eicher does not disclose that the substrate and/or microneedles are formed from flexible materials. Examiner respectfully disagrees. As is disclosed by Eicher in Column 4, Lines 12-30, "Materials which may be used to produce the container and the micro-pins include primarily thermoplastic materials...". Examiner contends that the broadly classified group of thermoplastic materials inherently include materials that are flexible. Even Applicant herself has admitted that, "materials commonly referred to as "plastic" may range from being extremely pliable..." in her response of February 17, 2005. Thus, Examiner maintains that Eicher does indeed disclose wherein the substrate and/or the microneedles are formed from flexible materials.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathryn L. Thompson whose telephone number is 703-305-3286. The examiner can normally be reached on 8:30 AM - 6:00 PM: 1st Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Nick Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KLT



NICHOLAS D. LUCCHESI
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700